REMARKS

In the Office Action dated June 16, 2009, the Examiner states that the claims of this application contain seven (7) groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I. Claims 1-34 and 52, drawn to an isolated hepatitis B variant and a vaccine comprising an agent from a surface component of an HBV variant.

Group II. Claims 35-38, 50 and 51, drawn to a method for determining the potential for an HBV to exhibit reduced sensitivity to a nucleoside or nucleotide analog.

Group III. Claims 39 and 40, drawn to a method for detecting an agent which exhibits inhibitory activity to an HBV which exhibits resistance or decreased sensitivity to one or more of ADV, LMV, TFV and/or FTC.

Group IV. Claims 41-43, drawn to a computer product for assessing the usefulness of a viral variant or biological sample.

Group V. Claims 44 and 45, drawn to a use of an HBV variant in the manufacture of a medicament for the treatment or prophylaxis of HBV infection.

Group VI. Claims 46 and 47, drawn to a method for detecting a variant HBV exhibiting an altered immunological profile.

Group VII. Claims 48 and 49, drawn to a kit for an assay for variant HBV comprising genetic agents capable of detecting an altered polymerase gene and/or an altered surface antigen gene on the HBV variant.

In order to be fully responsive to the Examiner's restriction, Applicants provisionally elect, with traverse, Group II, claims 35-38, 50 and 51, drawn to a method for determining the potential for an HBV to exhibit reduced sensitivity to a nucleoside or nucleotide analog.

However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the

Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

The Examiner alleges that the inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. Specifically, the Examiner contends that the shared technical features of the claimed invention include an isolated hepatitis B variant comprising a nucleotide mutation in a gene encoding a DNA polymerase and in S gene, a method for determining the potential for an HBV to exhibit reduced sensitivity to a nucleoside or nucleotide analog, and a method for detecting an agent which exhibits inhibitory activity to an HBV which exhibits resistance or decreased sensitivity to one or more of ADV, LMV, TFV and/or FTC. The Examiner alleges that these features are taught by Bartholomeusz et al. (WO03/066841 A1). Therefore, the Examiner concludes that Applicant's invention does not define a special technical feature when viewed over the prior art.

However, Applicants respectfully submit that unity of invention, not novelty, is the issue at hand. Applicants should be given the opportunity to argue the merits during prosecution, i.e., whether the claims are novel over prior art. Restriction of the claims at this stage would deny Applicants such an opportunity.

Further, Applicants submit that Groups I-VII represent different aspects of a single invention warranting examination in a single application.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined seven groups, one from another, as presented by the Examiner.

It is respectfully submitted that the present claims satisfy the requirements for unity of invention. Applicants respectfully urge that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all pending claims.

Respectfully submitted,

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